

Orthopedics This Week

week in review

4 Answer: Traction, a Screw, and MiMedx ♦
Question: What are three terrific new technologies or companies in orthopedics? We see new product ideas and companies every week, but these three recent candidates stood out for their innovation and practicality. See if you agree.

8 Wrong Data in Columbia Economic Study Blames Hip Surgeons ♦ Columbia University used the wrong data to conclude that fees paid U.S. orthopedic surgeons to perform hip surgery is a “main driver” of higher health care spending in the U.S. AAOS and Pearl-Diver found the right numbers and here they are. In fact, U.S. surgeons are paid less than many EU surgeons.



13 Reporter's Notebook ♦ Dr. Stephen Hochschul-er's take on why orthopedists are the weakest link; new life for old stem cells; and, are we soon going to need bake sales for residency fund-ing?



picture of success

26 Gunnar Andersson, M.D. ♦ The iconic Dr. Gunnar Andersson, Chair in Spinal Deformities at Rush University Medical Center, has driven much of the science behind spine care. And he has influenced the daily back health of drivers worldwide—he designed the seat in Volvo automobiles.



breaking news

- 16 Athletes Seek Treatment Abroad**
NuVasive to Buy Impulse Monitoring, Increases Shares
- Biomet 1Q12: Getting Better**
- Insurance Giants Cover Ankle Implant**
- MAKO's Robot Now Does Hip Surgery**
- Arthritis: Old Drug, New Use**
- 510(k) for Carticept's Navigator**
- Integra Launches Two New Products**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: The Euro crisis is a storm that will hit all shores, including orthopedics. With financial dominoes in Europe teetering, the institutional urge to sell ortho stocks will likely stay strong in October and November. As we've written several times, December and January look like the likely start of a 2012 ortho recovery.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Zimmer	27.75%	(8.02)%	2nd best PE, 4th best PE to Growth ratio and 2nd best future PE. #1 overall—again.
2	2	Medtronic	28.63	(6.61)	Lowest PE overall, lowest future PE overall but expected earnings growth is low (14th). So #2.
3	5	Smith & Nephew	22.80	(9.84)	Similar story to MDT, low PE valuations but also low earnings growth expectations. SNN has a history of upside earnings surprises however.
4	3	Stryker	25.23	(3.46)	Closes Concentric deal. SYK is performing better than most orthopedic companies. It is also using its cash strategically.
5	7	Johnson & Johnson	26.33	(3.52)	JNJ remains the perennial haven in any economic storm that washes through. Up 2 spots on Europe's crisis.
6	4	Orthofix	14.72	(9.40)	New CEO getting his team in place. Stock moving with the overall Ortho Peloton. Clearly, larger economic concerns rule right now.
7	6	Wright Medical	8.76	17.76	By far the best performer over the last 30 days. But the flush of excitement over WMGI's new CEO is settling down.
8	10	Integra	15.38	(10.13)	Stu and team aren't getting the respect they used to. 8th best PE, 8th best PSR but 13th in expected earnings growth.
9	8	Kensey Nash	34.24	(6.49)	Wall Street has high earnings growth expectations. But KNSY needs to also integrate its new purchases.
10	9	Conmed	9.65	3.88	More buyers than sellers in CNMD last month. But most analysts are looking for a down 3rd quarter earnings report.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Wright Medical	WMGI	\$17.64	\$695	17.76%
2 Bacterin Intl Holdings	BONE	\$2.09	\$83	12.37%
3 Conmed	CNMD	\$23.84	\$681	3.88%
4 Symmetry Medical	SMA	\$8.05	\$292	-1.35%
5 RTI Biologics Inc	RTIX	\$3.32	\$183	-1.78%
6 MAKO Surgical	MAKO	\$36.70	\$1,521	-3.42%
7 Stryker	SYK	\$47.88	\$18,593	-3.46%
8 Johnson & Johnson	JNJ	\$63.13	172,999	-3.52%
9 Exactech	EXAC	\$13.81	\$181	-5.86%
10 Synthes	SYST.VX	\$158.75	\$18,856	-5.91%

Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 NuVasive	NUVA	\$16.44	\$656	-29.32%
2 Trans1	TSON	\$3.07	\$86	-29.26%
3 CryoLife	CRY	\$4.26	\$120	-14.29%
4 Alphatec Holdings	ATEC	\$2.24	\$200	-13.51%
5 Integra LifeSciences	IART	\$34.96	\$962	-10.13%
6 Smith & Nephew	SNN	\$44.34	\$7,918	-9.84%
7 Orthofix	OFIX	\$32.38	\$596	-9.40%
8 ArthroCare	ARTC	\$28.81	\$791	-8.10%
9 Zimmer Holdings	ZMH	\$52.75	\$10,048	-8.02%
10 TiGenix	TIG.BR	\$0.90	\$82	-7.53%

Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Medtronic	MDT	\$33.31	\$35,341	10.16
2 Zimmer Holdings	ZMH	\$57.56	\$11,049	12.41
3 Johnson & Johnson	JNJ	\$62.71	\$171,897	12.82
4 Stryker	SYK	\$50.04	\$19,432	14.22
5 Kensey Nash	KNSY	\$26.43	\$225	15.02

Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Wright Medical	WMGI	\$17.64	\$695	25.20
2 NuVasive	NUVA	\$16.44	\$656	20.55
3 ArthroCare	ARTC	\$28.81	\$791	20.15
4 Synthes	SYST.VX	\$158.75	\$18,856	20.10
5 Exactech	EXAC	\$13.81	\$181	18.17

Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 Orthofix	OFIX	\$32.38	\$596	0.78
2 Integra LifeSciences	IART	\$34.96	\$962	0.79
3 Kensey Nash	KNSY	\$25.06	\$216	1.07
4 Zimmer Holdings	ZMH	\$52.75	\$10,048	1.17
5 Medtronic	MDT	\$32.83	\$34,668	1.24

Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 ArthroCare	ARTC	\$28.81	\$791	3.36
2 Johnson & Johnson	JNJ	\$63.13	172,999	2.29
3 Wright Medical	WMGI	\$17.64	\$695	2.05
4 Symmetry Medical	SMA	\$8.05	\$292	1.83
5 CryoLife	CRY	\$4.26	\$120	1.79

Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 Symmetry Medical	SMA	\$8.05	\$292	0.81
2 Exactech	EXAC	\$13.81	\$181	0.95
3 Conmed	CNMD	\$23.84	\$681	0.95
4 CryoLife	CRY	\$4.26	\$120	1.03
5 Orthofix	OFIX	\$32.38	\$596	1.06

Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$0.90	\$82	131.66
2 MAKO Surgical	MAKO	\$36.70	\$1,521	34.34
3 Synthes	SYST.VX	\$158.75	\$18,856	5.11
4 Bacterin Intl Holdings	BONE	\$2.09	\$83	3.60
5 Tornier N.V.	TRNX	\$20.07	\$786	3.46

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

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Answer: Traction, a Screw and MiMedx

By Robin Young



Standup Traction

Question: What are three fascinating new technologies or companies in orthopedics?

New product ideas and companies come across our collective desks at *OTW* every week. Three recent innovations in particular stand out. They are a traction system, a pedicle screw system (!), and a tiny but rapidly growing biomaterials company in Georgia named MiMedx.

We'll start with the blast from the past—an updated traction system for spine patients called the Standup Traction System (STS). Jud Carlson, an old friend of ours and one of the best known and regarded medical technology entrepreneurs in America, emailed us recently about the STS. The inventor is David Perrego, a chronic, low back

pain patient of Dr. David A. Petersen in Clearwater, Florida. Perrego had run out of treatment options and with help from both Dr. Peterson and Dr. Al Gadomski developed the STS. In total, about 500 patients have been treated with this new upright traction system.

Dr. Peterson tested the STS on 57 of his own patients who presented with a wide variety of back problems ranging from mechanical low back pain to failed back syndrome to radiculopathy secondary to HNP to spondylolisthesis, gross spinal instability and multi-level degenerative disc disease.

The Standup Traction System is FDA approved, has a reimbursement code in place for clinical use of lumbar traction and Cigna pays for home lumbar traction.

Vertical traction is not a new idea. The Sister Kenny Institute showed that vertical lumbar traction was more effective than horizontal traction in the 1980s using an electromechanical bed that could be moved from horizontal to vertical. They tested vertical traction on 30 patients diagnosed with low back pain resulting from lumbar disc herniation, disc degeneration and segmental instability. In the Sister Kenny study, 30 healthy individuals were also given the same traction procedure. According to the Sister Kenny study report, patients who'd been treated with vertical traction achieved disc distraction that was approximately 3 mm which compares

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to 0.89mm for horizontal traction, reported in other studies in each intervertebral space in both groups.

Traction is a method for distracting the spine and decompressing the intervertebral disc by applying a drawing or pulling force in a highly precise manner.

Unlike traditional horizontal traction systems, vertical systems like the STS use the patient's own body weight as the traction force and then use a fulcrum pad to direct the force of the body weight to specific spinal segments. Dr. Petersen treated a broad range of his patients three times per week for three weeks.

In Dr. Petersen's study, the STS mechanically reduced inflammation for 88% of the patients undergoing treatment regardless of the cause of their back pain.

Dr. Petersen accepted virtually all comers to try traction in his study. The patients came from every walk of life, made no changes in their current lifestyle, diet, exercise programs, medication profiles or activity levels during the study period. Dr. Peterson accepted no payment for the study but he is a non-majority shareholder in the company that makes the traction system.

Each patient was treated in the STS with three sets of traction. The doctor placed the fulcrum pad at the area most consistent with the patient's diagnosis. For example, a patient with pain at L4-5 would have the fulcrum pad placed at the level just above the L4-5 level to ensure that the force was being seen at the level of the patient's problem. The traction continued for 30-90 seconds per set.

Since 65% of the patient's body weight is focused at a specific spinal level, it is much more force than is generally seen during horizontal traction. One of the advantages of this approach is that the patients have total control over the amount of body weight that they apply. They can go for full suspension, which applies 65%, or partial suspension. They can also choose flexion or extension which adjusts the direction of the force.

The patients in the study ranged in age from under 20 years to over 71 years. As the following table illustrates, the range of complaints is very broad.

# of Patients Treated With VTS	Primary Diagnosis
16	DDD Multi-Level
11	Low Back Pain
10	Herniated Nucleus Pulpous
9	Prior Surgery
8	Spondylolisthesis
7	Stenosis
5	Failed Back Syndrome
2	Gross Instability

Source: Dr. David Peterson

The results of using this new form of traction were impressive:

- 88% of the patients reported both subjective and objective pain improvement
- 78% of the patients for whom surgery was their only presumed option had objective pain improvement
- 62% of the patients with radicular symptoms improved regardless of diagnostics or symptom duration.

For more information, drop Jud Carlson an email at: judc@bellsouth.net or call 561-756-2660.

The Expanding Orthopedics Pedicle Screw

A small Israeli start-up company, Expanding Orthopedics Inc. (EOI), has taken a technology developed by Israeli-based orthopedic surgeon Dr. Mark M. Levy and created an innovative new type of bone screw. Its first application is spine surgery, but this technology can be used in plenty of other places. With ten issued patents, this is a serious new twist on a well-established implant—the venerable bone screw.

How can the bone screw be improved? Levy's invention does it two ways—better bone fixation but without burning any bridges and no need to use bone cement to hold the screw in place.

The design is terrifically clever. Here's a picture. The key is the built-in operating mechanism. It allows the surgeon to open and close the wings of the screw. To use engineer-speak: the unique expansion mechanism allows for both deployment (expansion) for fixation and an active un-deployment for removal or repositioning of the screw.

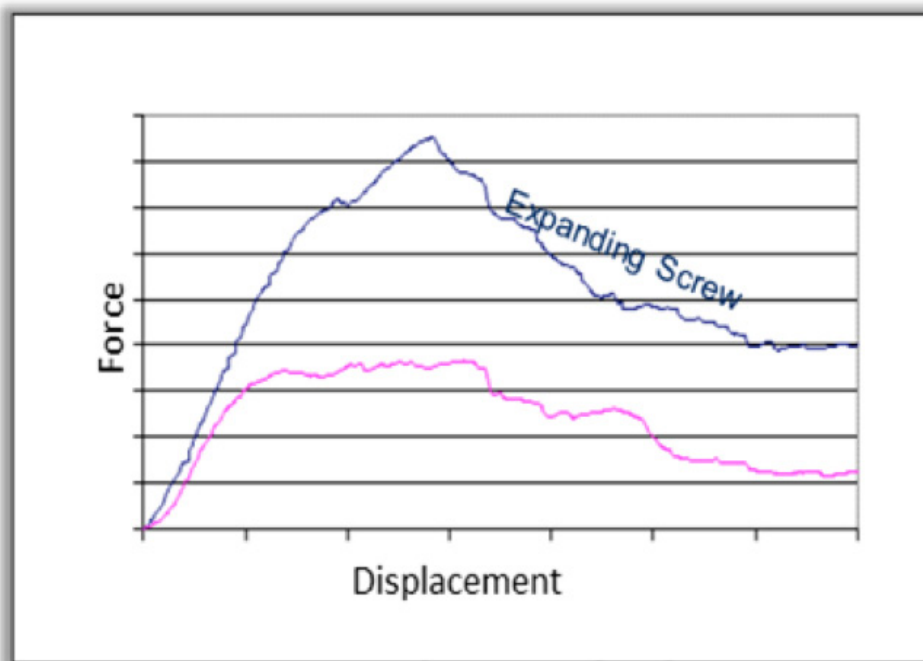


Expanding Orthopedics Inc.

The screw system is called "XPED" and it includes expandable screws, standard screws and instrumentation. XPED is starting to be used by a rapidly growing number of surgeons in Europe and Israel (it is CE marked). Initial reviews

from surgeons who've used it in the EU are excellent with the longest follow up of about a year.

"Initial anchoring and long-term fixation of the pedicle screw within the vertebral body are crucial for successful spinal fusion", said Ronald Rissel, M.D., Head of Spine Center, Stauferklinikum, Mutlangen, Germany. "A growing number of our patients undergoing spine fusion surgery suffer from an impaired bone condition as a result of chronic diseases, an unhealthy lifestyle and aging spine. In these patients, standard pedicle screws are sub-optimal, leading to a higher risk of screw loosening and resulting in a high re-operation rate. I expect the XPED expandable screw's innovative design to provide enhanced anchoring and potentially improve patient outcome."



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Not only is the screw easy to place and easy to retract if necessary, it also holds extraordinarily well. The attached chart shows how much force is required to pull the XPED screw out versus a standard pedicle screw. No cement required to achieve this kind of pull out strength.

EOI's CEO, Mr. Ofer Bokobza said: "The XPED Pedicle Screw System is a complete spinal implant system which defines a new standard of fixation with its enhanced anchoring capability. It allows the surgeons the flexibility to select the optimal fixation solution by indication and bone condition. The XPED's 4-wing screw is designed to increase the contact area with the bone, thus facilitating improved, immediate bone anchoring. Additionally, it allows for natural bone in-growth process which provides secondary natural fixation. The XPED Pedicle Screw System is CE marked and commercially available across Europe."

The system is not yet FDA cleared.

EOI announced recently that it had started a post-market, prospective study in Europe for the XPED system. Bokobza expects to enroll up to 50 patients in multiple centers. He also plans to follow the patients for up to 24 months post implantation using quality-of-life questionnaires and radiographic assessments. The renowned spine team of the Stauferklinikum in Germany is leading the study, with other centers due to join in the coming months.

Email Ofer Bokobza at ofer@xortho.com for more information.

MiMedx Group, Inc.

Parker H. “Pete” Petit built two hugely successful companies from scratch—Healthdyne, Inc. and Matria Healthcare, Inc. He would eventually sell Matria Healthcare in a transaction valued over \$1.2 billion and “retire.” In “retirement” Petit served as a director of Intelligent Systems Corp. and Logility, Inc. He was elected to the Georgia Technology Hall of Fame and funded a professional chair for Engineering in Medicine at Georgia Tech. He endowed the Petit Institute for Bioengineering and Biosciences at Georgia Tech and took numerous high profile board positions. But for “Pete” Petit, this wasn’t even living life at cruising speed.

So at a mere 69 years of age Petit came roaring out of retirement in 2009 at the request of a mutual friend of ours, Steve Gorlin, to take over a small struggling biologics company in Atlanta named MiMedx. Petit’s first move was to acquire Surgical Biologics, Inc., which is run by the immensely talented John Daniel and Randall Spencer.

MiMedx, whose stock trades under the symbol MDXG, announced early this year that it had raised \$5 million and then a couple weeks back announced a key partnership with Affirmative Solutions—a national distributor of spine, biologic and other medical products to the U.S. Veterans Administration and the Department of Defense.

What makes MiMedx so special?

Besides “Pete” Petit, this spit fire of a company has one of the most interesting biomaterial portfolios of ANY company in orthopedics. Some of the larger firms should take notice—it’s got four power house product platform technologies in it.

CollaFix: This is a remarkable collagen technology which mimics in composition, structure and mechanical properties the musculoskeletal system. The technology is based on collagen fibers about the size of human hair which are fabricated in continuous lengths of spooled fibers. These are cross-linked which makes them incredibly strong, biocompatible and long lived after implantation yet the material remains resorbable and biocompatible. In a sense, CollaFix reminds us of a collagen-like Gore-Tex or GraftJacket.



MiMedx Group, Inc.

HydroFix: HydroFix technology originated at the Georgia Institute of Technology in Atlanta, Georgia. In the late 1990’s, several graduate students and Professor David Ku, M.D., Ph.D. discovered a method for producing a very durable, strong but also easily modifiable polymer hydrogel into virtually any shape. The material mimics the properties of soft tissue and it can be manufactured with material properties that are tailored to just about any orthopedic or vascular implant application. In specific formulations the material may prohibit cellular attachment and tissue ingrowth.

AmnioFix: Our personal favorite, this is a biologic amniotic membrane which has been processed through Surgical Biologics’ proprietary Purion process and which combines cleaning, dehydration and sterilization to produce a safe, technically sterilized allograft utilized for soft tissue surgical repair and healing in various ophthalmic, orthopedic, spinal surgery, dental and sports medicine applications.

EpiFix: EpiFix, the branded tissue produced by MiMedx and processed through Purion, is a biologic implant specifically processed from amniotic tissue to offer a wide variety of wound healing and wound care options.

For more information about MiMedx please contact Pete Petit at 866-477-4219. ♦

Wrong Data in Columbia Economic Study Blames Hip Surgeons

By Walter Eisner



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Higher fees paid to orthopedic surgeons for performing hip replacements in the U.S. is a “main driver” of higher health care spending in the U.S. than in Canada, France, Germany, the United Kingdom and Australia.

That’s the stated conclusion of a study published in the September issue of *Health Affairs* by two political science professors from Columbia University. One of the authors, Sherry Glied, Ph.D., has since become the assistant

secretary for planning and evaluation at the U.S. Department of Health and Human Services.

Disputed Fees Data

There’s just one big problem with their conclusion. The evidence of higher fees paid to U.S. orthopedic surgeons for hip surgery just doesn’t add up.

Glied and her colleague, Miriam Laugesen, Ph.D., in the study, titled: “High-

er Fees Paid To US Physicians Drive Higher Spending For Physician Services Compared To Other Countries” (*Health Affairs*, 30, no.9 (2011):1647-1656), compared fees paid to docs by public and private payers for primary care office visits and hip replacements in the countries noted above.

\$1,634 or \$962

The authors claim that public payer Medicare, paid U.S. orthopedic sur-



Miriam Laugesen, PhD



Sherry Glied, Ph.D

geon 70% more for hip replacements than public payers paid their counterparts in other countries. As evidence, they report that Medicare reimbursed surgeons an average of \$1,634 for a hip replacement in the U.S in 2009. See their report's table 1 for comparison fees paid to physicians for hip surgery.

Table 1: Fees paid by public payers to physicians performing hip surgery.

Country	Fee (\$) 2009
U.S.	1,634
Germany	1,251
UK	1,181
Australia	1,046
France	674
Canada	652

Source: Laugesen, Glied

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We double checked the U.S. numbers cited by the Columbia study with our sister company, PearlDiver Technologies, Inc. Analysts at PearlDiver found that the average payment to Medicare by hospitals in 2009 in the U.S. for hip replacements was closer to \$960 than \$1,600—\$960, by the way, would be *less than* Australia, Germany or the UK.

Charging Records Versus Physician Fee Schedule

To get that number, PearlDiver analysts pulled up the 2009 CMS Carrier Standard Analytical File which holds a random 5% sample of all physicians charging records in Medicare and looked for all instances of a physician submitting a claim for CPT code 27130 (which is the most standard code use by surgeons when charging for a hip replacement).

We asked Dr. Laugesen about the discrepancy. To her credit, she went back and verified her data. She told us the source of her study's \$1,634 number was the Medicare Physician Fee Schedule and stands by that number. Dr. Laugesen also told us that their numbers included direct payments to beneficiaries.

Dr. Laugesen wrote us, "I have carefully reviewed the data used in the study published in *Health Affairs*. Based on a review of the fees paid by Medicare under the Physician Fee Schedule for these services, and a review of the data on Medicare expenditure[s]...I find that the price and average expenditure is [close to the number in her study (\$1,600)]."

According to Centers for Medicare and Medicaid Services (CMS), the Physician

Fee Schedule is a, “comprehensive listing of fee maximums is used to reimburse a physician and/or other providers on a fee-for-service basis.” In other words, the maximum allowed for reimbursement, not what is actually paid.

PearlDiver analysts went to CMS’ ResDAC (Research Data Assistance Center) to double check and found that payments to beneficiaries were a very rare event. After tweaking numbers for denied claims and the rare payment to a beneficiary, PearlDiver came up with an average payment of \$962 to a surgeon in the U.S. for performing a hip replacement surgery.

According to Laugesen and Glied, the average public payment to surgeons in the five comparative countries for a hip replacement was...wait for it...\$960.

Columbia’s Disputed Conclusion

Clearly, this evidence shows that payments to surgeons for performing hip replacements in the U.S. is not a “main driver” of why health care spending is higher in the U.S. than in other countries.

Ben Young, the President of PearlDiver, told us that the average hospital charges for a total hip replacement from Medicare is about \$9,700. In 2007, reimbursement was over \$10,700. “So you can see that even hospital reimbursements for this procedure have been dropping over the past few years,” said Young.

Surgeons and Hip Maker Respond

PearlDiver’s evidence was not the only challenge to the Columbia study’s conclusion that hip surgeons were the culprits of higher spending.

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We asked surgeons, through American Academy of Orthopaedic Surgeons (AAOS), and the biggest hip maker in the world, Zimmer Holdings, Inc. about the Columbia conclusion.

AAOS: Surgeon Payments Are Minimal and Declining

The Academy told us that the study, “failed to point out that physician fees are a very small piece of total U.S. health-

care costs (according to the Congressional Budget Office Medicare payments for physician services comprise 13% of total Medicare spending). Instead, the authors erroneously attribute the significant increases in total U.S. healthcare expenditures directly to payment rates for physicians.”

“Medicare payments for physician services have remained virtually flat or actually decreased in the last decade



RRY Publications/Andrew Huth

while healthcare expenditures continue to steadily rise. For instance, the Medicare payment for a hip replacement surgery has decreased by 7% in nominal (actual) dollars and 32% in real (inflation adjusted) dollars since 2000, while total Medicare expenditures have almost doubled in the same time period, according to the Centers for Medicare and Medicaid Services (CMS),” continued the response from AAOS.

In conclusion, the Academy told us that the study compares costs for physician services across six different countries. “International healthcare cost comparisons are notoriously difficult to make due to variations across countries in practice setting, medical liability rates, the number of insured citizens, and each country’s economic complexities.”

Zimmer: Flawed Study, Wrong Conclusion

Zimmer Holdings which has almost 25% of the world’s hip market share, told us through their health economics team that data, as the authors of the Columbia study noted, must be pieced together from disparate, often conflicting sources. They say this is apparent in the study’s use of \$3,996 (for private payment for hip replacement surgery in the U.S. from HealthGrades).

“Zimmer’s analysis of more than 15,000 actual hip replacement claims from the Thomson Reuters MarketScan Commercial Claims Database has demonstrated that the average physician hip replacement reimbursement in 2008 was approximately \$2,400.

Zimmer says the study failed also to factor in payer mix—the majority of hip replacements in the U.S. are funded

via Medicare. Thus, they conclude the weighted average physician payment per procedure is approximately \$1,800. “This payment falls squarely in the payment ranges noted by the authors for Australia and UK.”

“Further analysis by Zimmer has shown that unadjusted Medicare reimbursements have actually fallen while private payments have risen only modestly over a seven-year period. During this same time period, hospital reimbursements have risen substantially.”

Another flaw of the study’s calculations, according to Zimmer, is the omission of variables such as professional liability (malpractice) insurance and administrative expenses.

“In the control markets, single payer systems dominate and thus the corresponding administrative burden is lower than in the U.S. where there are several hundred payers, all of whom establish their own policies. Morra, et al., in a study published in the August 2011 edition of *Health Affairs*, estimate that U.S. physician burden for payer interactions is \$27.6 billion higher than their Ontario, Canada, counterparts in a single-payer system.

“Regarding malpractice, the U.S. is by far the most litigious market in the assessment and there is a corresponding effect of additional required coverage and costs. While one could argue this is part of practice expenses, the specific effect associated with malprac-

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“... expenses was not expressly called out.”

The Zimmer team also found a problem with the study’s lack of considering of excess demand within the markets.

“In many countries, surgical reimbursement rates are set by policy and can be treated as predetermined. Some countries lack information on commercial surgical reimbursement rates as the study noted. The article notes per capita demand. However, it does not discuss the excess demand of each country. In most cases, this excess demand does not enter into the world market for surgical procedures. Thus, in this case, the sum of all excess demand is not equal to zero by market clearing. This effect was not taken into account when determining the market price for the procedure.”

“We disagree with the study’s conclusion,” said the Zimmer response.

The surgeons and hip makers agree that researchers and policymakers should look somewhere else for a culprit to higher spending.

“The authors did not provide adequate total expenditure per market and failed to correctly characterize reimbursement for orthopaedics for major joint replacement. Physician payments are by no means the most significant driver of spending, especially for hip and knee surgeons, whose reimbursement has in fact declined while the number of surgeries has doubled since 2000 and administrative costs and system inefficiencies continue to strain the U.S.

health care system,” concluded the Zimmer statement.

What was not debated was that U.S. orthopedic surgeons are paid more annually than their counterparts. According to the Columbia study, U.S. orthopedic surgeons earned about \$442,450 per year, followed by the \$324,138 earned by British orthopedic surgeons. French orthopedic surgeons are at the low end and earn about \$154,380 annually.

Public Policy Impact

What is in dispute is the conclusion from the challenged study which might

find its way into the public policy decision-making process at Medicare.

As we noted, Dr. Glied is now the assistant secretary for planning and evaluation at the U.S. Department of Health and Human Services (HHS). The paper was written before she was appointed to that position and doesn’t reflect the views of HHS, according to a disclaimer published with the paper.

The Columbia study was supported by an Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation and by a grant from the Commonwealth Fund. ♦

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Reporter's Notebook

By Elizabeth Hofheinz, M.P.H., M.Ed

Dear OTW Reader:

Dr. Stephen Hochschuler's take on why orthopedists are the weakest link; new life for old stem cells; and, are we soon going to need bake sales for residency funding?

A Stryker Goes -Selling. There are a few descendants of Dr. Homer Stryker, founder of the eponymous company, who own a large percentage of the company's stock...but at least one is getting rid of portions of said stock. Ronda E. Stryker, a company director and Homer's granddaughter, according to an August 12, 2011 article on marketbrief.com, this director—the only member of the family to serve on the Stryker board—sold 1,465,000 shares of company stock for a total of \$84,547,826. Why? We do not know. But this 57-year-old is according to Forbes.com, believed to be among the anonymous donors to the Kalamazoo Promise, a scholarship program that provides college tuition to all Kalamazoo Public School students.

Egos Harming the Field? Stephen Hochschuler, M.D., famed founder of the Texas Back Institute, says that despite the “squeeze” on orthopedics, he would do it all again. “But it's tougher now,” Dr. Hochschuler tells OTW. “To come out of residency with \$250,000 in debt and no sign of paying it off anytime soon is less than optimal. But we orthopedists are the weakest link. Why? Because we never organized ourselves. **Physicians are more concerned about how another doctor is doing than how their field is doing.** And residents

don't get involved in things that affect them overall...they are more concerned about why the other guy made chief resident.”

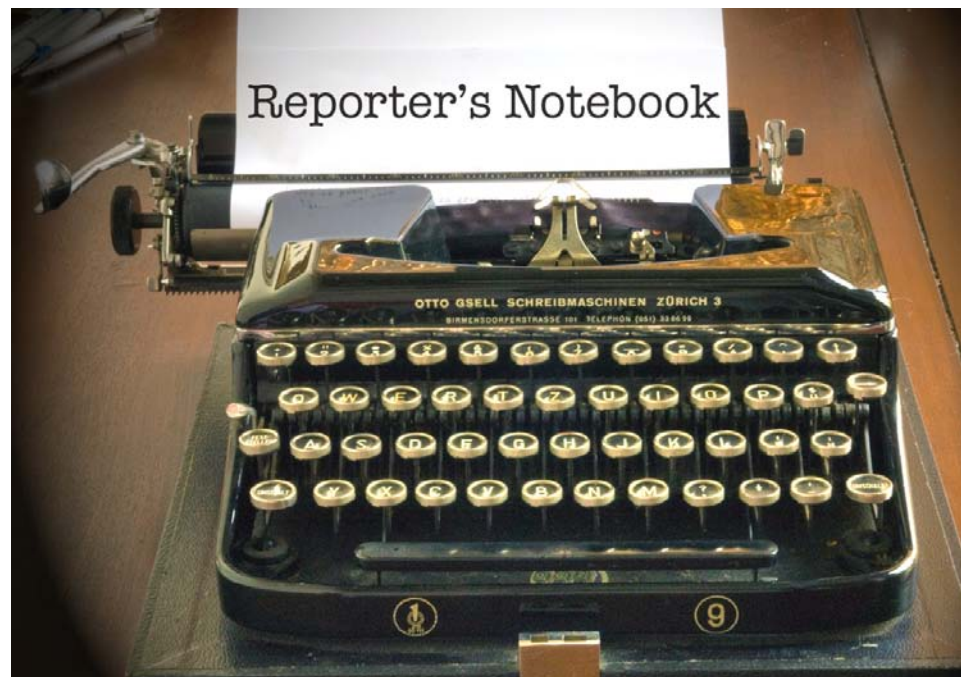
Residents Driven Around the Bend?

Giving a behind-the-scenes look at the duty hour melee, a resident tells OTW, “It's really causing havoc with how much residents can learn. Interns in particular are very limited in what they can do. We rely on them to take call at night with us—both for us and so they can learn...but that is really restricted now. **You have a situation where they are on call but it's 10pm and they come in to do an ankle reduction, but then learn that they have exceeded their hours. I haven't seen people flout the rules, but it has been talked about as**

a possibility. One of the ideas behind these regulations was that residents would go home and read. Instead, we are spending time putting our schedules into a computer in order to maintain compliance. Overall, the situation is ridiculous...someone may not have worked all afternoon, but because it's after midnight they can't come in. In several years the orthopedic universe will realize that residents are lacking in skills and that it is unsafe for the general populace.”

Fully Trained Isn't Fully Trained.

Other parties involved with residency aren't so happy either...one tells OTW, “Several weeks ago the Residency Review Committee released what it considers to be the ‘minimum’ number of



Wikimedia Commons

surgeries for certain procedures. When I look around—and take into consideration these new ‘minimums,’ there is no way that residents coming out of programs are fully trained. You know, in Europe the duty hours are down to about 50 hours a week. If the trend continues in our country then we will just have to extend residencies. **When someone finishes residency the program signs off on the person being a qualified independent practitioner of orthopedic surgery. That is really a stretch nowadays.** And it doesn't do much good to police duty hours...if a person is going to fudge his or her time, then they will find a way to do that.”

Car Wash, Bake Sales for Residency Education? Brian Parsley, M.D. tells *OTW*, “There is a firestorm of concern about graduate medical education funding. The severe budget cuts in federal and state funding mean that we have to either get organized and fight for the restoration of those funds—or, we have to find alternative funds. Some people are predicting that in ten years there will be **no** funding for residents and fellows. Although the ACGME, residency programs, and the specialty societies have this issue on their radar, so far no one has come up with an effective idea. **At Baylor they recently sent a note around saying that if you have a fellowship or residency slot that was not filled that you can't fill it without the administration's approval.** That is a huge change. In the past if you had an open slot after match day you could continue to search for applicants and had complete freedom to fill that slot. And we think we have ‘manpower’ problems now!”

Feds Overlooking the Obvious? A Ph.D. involved in orthopedic education tells *OTW*, “The Obama plan to cut 30%

of the budget for graduate medical education is top on everyone's mind. The American Association of Medical Colleges has recently done a survey about how this would affect the financing of graduate programs. One of the things all institutions must ask these days is, ‘How could we do this with less money and at the same level of quality?’ At a time when we need to be training more orthopedic surgeons (because of baby boomers needing joint replacements, for example) we are going to have to make do with fewer doctors. **It's too bad that the powers that be aren't thinking about the big economic picture...if we were able to keep older people functioning well then their medical care would be less of an economic burden.**”

New Life for Old Stem Cells. Evan Flatow, M.D., Chair of Orthopaedics at the Mount Sinai Medical Center, tells *OTW*, “In my lab we have recently found out that stem cells age as we do. This is one of the reasons that older people with tendon injuries don't heal as well—they have fewer stem cells and they don't reproduce as well. BUT, there are certain genes that you can turn on that make old stem cells act like young stem cells. If you just dump stem cells into tendon injuries it doesn't do much; you have to turn them on and give them the right biologic signals. We are now working on it with a broader group of patients, and are applying for a federal grant that will enable us to manipulate the stem cells.”

Doors Opening for Younger Shoulder Surgeons. In a major shift, says a shoulder and elbow surgeon, the American Shoulder and Elbow Surgeons (ASES) is on the verge of opening up its membership. He tells *OTW*, “The ASES has traditionally been a closed society, i.e.,

meetings have been restricted to members. **We realized that we were one of the few societies in all of orthopedics to remain closed...there is a new initiative to open our society and make it more inclusive.** That way younger, less established people can participate and become involved in the growth of our society. We didn't want to be perceived as elitist. Also, inclusion of more members would allow us to extend our educational mission.”

Cutthroat Orthopedics? John Kelly, M.D., Associate Professor of Clinical Orthopaedic Surgery at the University of Pennsylvania, is seeing an ugly side to the field these days. He tells *OTW*, “I've seen several instances of people driven off staff at different institutions because of increased competition in the field. In one instance I was trying to counsel a peer who had been

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reported to the medical board. It was a competitor group that did the reporting—and he *was* exonerated. Resources ‘out there’ are dwindling...and this is bringing out the worst in people.”

Quick, Learn a New Implant! An orthopedist in academic medicine tells OTW, “A fundamental question is, ‘How are hospitals going to align with doctors to cut costs?’ I already see hospitals putting pressure on providers, saying, ‘We need to cut costs.’ Hospitals are saying, ‘Help us renegotiate contracts with the vendors’—or, ‘Use less expensive implants.’ One of the biggest healthcare consortiums in my city owns several hospitals. They are telling the physicians, ‘Here are the three acceptable vendors for total joints.’ I have some colleagues at these institutions whose ‘normal’ implants were not selected and so they had just one month to learn new implant systems.”

HSS? No Germs Allowed! Hospital for Special Surgery (HSS) is reporting that it is the only hospital in New York State with an infection rate that is significantly lower than the state average for hip replacement or revision surgeries. Surgeons at HSS performed the most hip replacement surgeries in New York State. During each of those surgeries there was an infection prevention nurse who oversees the operating room. **As indicated by HSS, also helping matters is that each room is standardized, improving efficiency and lowering surgical time by having surgical tools laid out and organized in the same order.** Additionally, HSS minimizes patients’ exposure to contaminants by isolating them from the environment by a specially designed Plexiglas enclosure (helping to improve airflow and to restrict excess personnel at the surgical field). ♦

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company

Biomet Reaching for Market Growth

Biomet, Inc.'s reported sales rose 4% to \$664.6 million during the last quarter (1Q12). Net sales were flat on a constant currency basis.

Biomet's President and CEO Jeff Binder told analysts during an October 6 conference call that the story of Biomet is about being in a soft market and coming back to market growth. Biomet had lost market share to competitors during the last quarter.

Reported hip sales were up 7%, knees up 2% and extremities grew by 19%. Reported spine sales continued to be a challenge for the company and declined by 10%.

The growth in hip sales was attributed to market demand for the Arcos Modular Femoral Revision System, Active



The Golden Hand/Wikimedia Commons

Articulation E1 Mobility Hip System, and the Taperloc Complete Hip Stem.

Reported sales declined 1% in the U.S., while European sales increased 8%. The remaining reported international sales rose 20%.

Said Binder, "We executed well with our new product launches in hips during the quarter and we're pleased with the improved sales results." He expects to see similar improvements in knee sales later this year and into next year as the company launches several new products in the second half. Binder also announced that the company is beginning to report sports, extremities and trauma sales as a distinct category in keeping with recent organizational changes.

PODS, Improving Markets and Device Tax

Binder made special note of competition from physician-owned distributorships (PODs) as a contributing factor for the decline in spine sales. He said the growth of PODs accelerated during the quarter and are beginning to expand from spine products to total joints. He believes the POD models he has seen are "highly problematic" from an anti-kickback perspective and are a "really bad trend." He told analysts that he was disappointed by a "tepid" response

from the Office of Investigator General (IOG) to requests from some U.S. Senators for additional guidance on PODs.

To read Binder's latest blog discussing PODs, click here: <http://www.biomet.com/corporate/ceoBlog/postDetail.cfm?postID=68>

While not "wildly" optimistic, Binder said he was cautiously optimistic that the orthopedic market had not deteriorated and might be about to improve, "ever so slightly." Binder's comments came on the heels of a recent AdvaMed study that predicted demand for medical devices will decline due to a 2.3% medical device tax scheduled to kick-in in 2013 under the Accountable Care Act (ACA).

Wall Street: Ortho Stabilizing

BMO Capital Market analyst Joanne Wuensch said Biomet's results were "somewhat better" than the prior two quarters and leads her to believe that the orthopedic market is stable sequentially.

Larry Biegelsen, Wells Fargo's analyst, said the key takeaways from Biomet's earnings release were that overall large joint reconstruction growth improved slightly compared to the prior two quarters, knee growth continues to face greater pressure than hip growth, and extremities continues to be the fastest growing ortho segment.

— W E
(August 30, 2011)

Biomet, Inc. 1Q12	Sales (\$ in millions)	% Change
Total Reported Sales	664.6	4%
Large Joints	397	5%
Knees		2%
Hips		7%
Sports, Extremities, Trauma	80.1	11.0%
Spine & Bone Healing	76.1	down 10%
Dental	59.3	5.0%
Other	52.1	9.0%

Source: Biomet, Inc.

NuVasive to Buy Impulse Monitoring, Increases Shares

NuVasive, Inc. has agreed to purchase Impulse Monitoring, Inc. for \$40 million in cash and \$40 million in stock.

The announcement on September 28 came on the same day the company announced that its shareholders had agreed to increase the authorized shares of common stock from 70 million to 120 million shares. The news comes on the heels of the company's first round loss to Medtronic, Inc. in a patent fight. The company's stock price fell from around \$20 per share to \$15 per share within days of all the announcements.

Impulse Monitoring, Inc.

The company said the acquisition of Impulse will complement its existing NeuroVision nerve monitoring system. "The strategic move to acquire an IOM (inter-operative monitoring) service provider will increase XLIF penetration and further drive lateral market share by increasing the number of neurophysiologists able to setup use of NeuroVision. Impulse Monitoring employs over 150 neurophysiologists while NuVasive has over 300 spine specialists in the field. As well, Impulse Monitoring will expand NuVasive's presence into IOM services with a new revenue stream," stated the company press release.

The company also believes the acquisition opens up a significant revenue growth opportunity in the \$800 million IOM market. According to the company, only 50% of spine procedures currently undergo IOM. They expect that market to grow approximately 15% annually of the next few years.



Andrew Huth for RRY Publications, LLC

Alex Lukianov, Chairman and CEO of NuVasive, said during a conference call with analysts, "We intend to be the hospital's go-to provider for neuro-spine monitoring."

Lukianov: "Penetration Opportunities"

The chairman also said the acquisition will increase XLIF penetration opportunities. "This acquisition will augment our leadership position within neuro-monitoring by enabling NuVasive to offer additional best in class services, including operating room clinical support of neuromonitoring and professional neuromonitoring oversight. The service will expand our relationships with our surgeon and hospital customers and foster incremental revenue opportunities."

Depending on when the transaction closes, NuVasive anticipates that Impulse will contribute over \$8 million to fourth quarter 2011 revenue

and is growing at an annual run rate approaching \$40 million.

Wall Street Caution

Joanne Wuensch, BMO Capital Markets' analyst, summed up Wall Street's view of the deal when she wrote that the [Impulse] sales force captures additional physicians once freed from neuromonitoring responsibilities and neurophysiologists open the doors to new hospitals and new procedures (e.g., scoliosis).

"The combination could benefit NuVasive's presence on the East Coast, where Impulse's 150 neurophysiologists are in hospitals where NuVasive has yet to make a dent. These do not seem like wild propositions to us, but we question the timing of the acquisition given its cash position in the post-Medtronic litigation environment, as well as whether the increased sales can offset the drag of a lower-margin franchise."

—WE (October 4, 2011)

legal

Health Law on Fast Track to Supreme Court

It's beginning to appear that the U.S. Supreme Court could hear the Affordable Care Act (ACA) challenge from 26 states' Attorneys General during the court's new term beginning this October. That might mean a decision about the constitutionality of the insurance mandate and the entire law before the next election in 2012.

We note that physicians owning hospitals also have a stake in this fight, as the law also includes prohibition against an expansion of such hospitals.

On Monday, September 26, the Justice Department, according to published

reports, said it would not ask a federal appeals court in Atlanta to review that court's three-member panel ruling against the ACA in August. Had the Obama administration asked for a full review by all 11 judges on the appeals court, it would likely have delayed a Supreme Court hearing until at least 2013.

Now, if the Justice Department appeals directly to the Supreme Court, and the Court agrees to hear the case, a decision would likely come next summer.

There are currently two other appeals court decisions in favor of the Act waiting to be appealed to the Supreme Court.

On Wednesday, September 28, the 26-state coalition petitioned the Supreme Court to take the case and

declare the entire new healthcare law as unconstitutional. The appeals court had ruled only that the insurance mandate was unconstitutional.

With split appeals court decisions it's almost certain the high court will hear the case.

—WE (September 28, 2011)



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biologics

Athletes Seek Treatment Abroad

In the wake of reports that football star quarterback Peyton Manning went to Europe for an experimental stem cell treatment for his neck injury, NFL wide receiver Terrell Owens is said to be in South Korea for similar treatment for a knee injury.

The search abroad by professional athletes for stem cell treatment of injuries is "emblematic of a major phenomenon occurring right now," said Dr. Joshua Hare, director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine. He is not involved with either player's therapy.

Owens is expected to receive treatment at the Chaum Anti-Aging Center under the care of Doctor Lee Jung-no to repair a severely damaged anterior cruciate ligament. Owens was previously treated by Dr. James Andrews of the Andrew Sports Medicine and Orthopedic Center, Birmingham, Alabama.

According to the September 20 press release in *The Korea Times*, Dr. Lee Jung-no confirmed that, "Dr. Andrews advised Owens to contact Chaum Anti-aging Center first, which then led him to visit our office here."

Jung-no also stated that Owens is to start "with therapy Monday fol-

lowed by the collecting and storing of his stem cells the next day." The entire process is expected to take a total of three days. Owens reportedly hopes the autologous stem cell treatments will get him back in the game.

—BY (September 27, 2011)



Wikimedia Commons and Denis Laflamme

large joints

510(k) for Carticept's Navigator

Ultrasound in the pursuit of ultra-safe...Carticept Medical, Inc., a company focused on innovations for the treatment of cartilage injuries and osteoarthritis, has announced receipt of 510(k) clearance from the FDA to market its Navigator Delivery System (Navigator DS) in the United States. The Navigator DS is a computer-controlled drug delivery system with integrated ultrasound guidance designed to increase the efficiency, accuracy and safety of administering pain-relieving medications for joint pain.



Carticept Medical, Inc.

"Minimally invasive and cost-effective injections can delay and in some cases eliminate the need for surgical intervention," said John S. Reach, Jr., M.Sc., M.D., director of the Yale Foot and Ankle Section and assistant professor in the department of Orthopaedic Surgery, Yale University School of Medicine, New Haven, Connecticut, in the October 4, 2011 news release. "Recent studies have demonstrated greater accuracy with improved function and decreased pain in patients receiving ultrasound-guided injections. The Navigator DS automatically prepares the medication dose, guides accurate needle positioning prior to drug delivery, and simplifies record-keeping—allowing me to spend more quality time with each patient."

The Navigator DS is a comprehensive drug delivery system for convenient operation by a single clinician. The Navigator DS prepares and delivers physician-prescribed injections from standard multi-dose anesthetic and steroid drug vials, eliminating needle exposures to healthcare workers and minimizing the potential for contamination of the medication. Additionally, the automated system helps to ensure accurate dose preparation and saves significant labor for a busy physician practice. The ultrasound screen provides the physician with real-time visualization of the needle position, fluid delivery process and prescription volume. After the injection is delivered, the system records the treatment data and automatically creates a record for transfer to an electronic record management system.

"The FDA clearance of the Navigator DS provides physicians with a complete, computer-controlled intelligent injection system," said Timothy J. Patrick, president and chief executive officer of Carticept. "In addition to its use in

sports medicine and orthopaedics, we believe the technology has future applications in anesthesiology, radiology and other specialties that require accurate dose delivery."

Timothy Patrick told OTW, "Carticept is committed to providing physicians with the tools they need to improve clinical outcomes and enhance the physician and patient's procedural experience. The Navigator DS computer-controlled injection system with integrated image guidance is designed to increase the accuracy, efficiency and safety of musculoskeletal injections, which will ultimately lead to better patient care. In addition to its use in sports medicine and orthopaedics, we believe the technology has future applications in anesthesiology, radiology and other specialties that require accurate dose delivery."

—EH (October 5, 2011)

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Insurers Making Own Hips & Knees?

Three Australian health insurers have teamed up to develop less expensive generic hip and knee replacements. Company executives believe this will eventually cut their growing prostheses costs by \$1 billion a year. The developers are basing the design of the generic hips on older products and selling them for 20% to 25% less than rival hips—a saving of around \$2,480 per device.

The three health funds, Medibank Private, BUPA and Australian Unity have provided 90% of the capital funding for the new prostheses company, called Joint Research, to develop the generic hip and knee replacements.

Medibank Private Managing Director George Saviddes says the number of hip and knee replacements will increase in coming years as the population of those older than 65 doubles while the number of people older than 85 quadruples. He expects that, in the next generation, people will be using an average of three

of these devices in their lifetimes. “When you add those three things together, it’s looking like a very steep curve. But we have an opportunity to do something about it,” he says.

Saviddes calculates that if out-of-patent equivalent joint replacements can gain one-third of the market, his health fund will save \$100 million a year. Within ten years the three health funds could be saving \$1 billion a year which would help keep insurance premium costs under control.

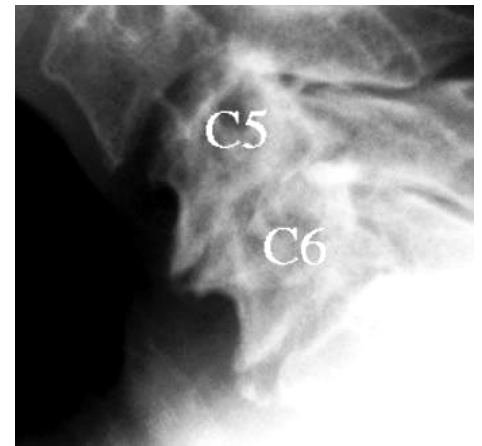
The Australian health safety watchdog, the Therapeutic Goods Administration, has approved two of Joint Research’s generic hip devices. One is cemented and the other is cementless. The cemented generic hip is based on the off-patent Exeter hip which was developed more than 40 years ago. Joint replacement registries show it has one of the best long-term histories of clinical success. Since the hips went on sale in August, Joint Research has sold 250.

—BY (September 30, 2011)

Arthritis: Old Drug, New Use

Hummm. Nice surprise... Researchers from the University of Rochester Medical Center have discovered that Forteo, already approved to build bone mass in patients with osteoporosis, also builds cartilage around joints and could potentially be used to treat countless arthritis patients. The findings are published in the September issue of *Science Translational Medicine*.

“We believe that a potential alternative to this cycle of pain and reduced quality of life has gone unnoticed for the past decade,” said study co-author Michael J. Zuscik, Ph.D., associate pro-



Wikimedia Commons, A.E. Francis, and National Institute of Health

essor, Department of Orthopedics & Rehabilitation, Center for Musculoskeletal Research at URM, in the September 21, 2011 news release. “Given that Forteo is already FDA approved, our experimental findings make a compelling case for further clinical study of this drug in the context of arthritis.”

Dr. Zuscik and co-author Randy N. Rosier, M.D., Ph.D., professor of Orthopaedics & Rehabilitation, lead a laboratory that investigates osteoarthritis (OA). They and their team noticed that



Wikipedia.org and Medibank.com.au

occasionally, when a patient suffered from both disorders—osteoporosis and osteoarthritis—the symptoms of arthritis would improve after taking Forteo for osteoporosis.

The team used a mouse model for post-traumatic knee osteoarthritis and demonstrated in several laboratory experiments that when Forteo was given daily for one month, the injured cartilage became as much as 32% thicker, cell production was enhanced, and genes and molecules associated with the degeneration of cartilage were suppressed.

The researchers also reviewed OA patient information from government databases. Of 4,000 people diagnosed with knee arthritis, they found 14 who were also taking Forteo for osteoporosis. This small group of people reported less arthritis pain and a higher ability to function than a matched population of patients who were not taking Forteo.

The team notes that Forteo carries a black-box warning because it has been found to cause an increased risk of the bone cancer osteosarcoma in rats. It is thus to be determined how long the protective/regenerative effect on cartilage persists after treatment is stopped.

Dr. Zuscik told OTW, “The biggest milestone was the completion of the experiment which showed that Forteo could enhance the thickness of articular cartilage during progressing osteoarthritis in the mouse—there is no other therapy or treatment that has been shown to induce chondroregeneration like we saw in that experiment. The plan moving forward is to perform an initial pilot clinical trial with OA patients with the aim of collecting preliminary data for a near future placebo-controlled trial.”

—EH (September 27, 2011)

MAKO's Robot Now Does Hip Surgery

After receiving FDA clearance in February 2010, MAKO Surgical Corp.'s RIO Robotic Arm Interactive Orthopedic System is now commercially available for use in total hip replacement surgeries.

MAKO has had a robotic system for partial knee resurfacing procedures for five years and now offers surgeons and patients the same technology for hip surgery.

The system is called MAKOplasty Total Hip Arthroplasty.

The surgeon's ability to accurately align and position implants is well known as a potential source of complications associated with conventional hip replacement surgery. According to a September 19 statement from MAKO, a recently published Massachusetts Gen-



MAKOplasty Total Hip Arthroplasty/MAKO Surgical Corp.

eral Hospital study reported that, over a sustained period of study of 1,823 hips, only 50% of acetabular cups were positioned in the acceptable range.

Lawrence Dorr, M.D., founder and medical director of The Dorr Arthritis Institute in Los Angeles, said the system, “provides a significant advantage to me as a surgeon and to my patients. It provides quantitative knowledge for what were difficult judgment decisions inherent in manually performed operations. When I finish a hip replacement I no longer am anxious to see the X-ray because I know I’ve got the implants, leg length and offset correct. It makes recovery easier for patients, including their comfort, activities and protection from dislocation. This robotic guided operation is better for both me and my patients.”

Maurice Ferré, M.D., president and chief executive officer of MAKO, told *OTW*, “The quantification of cup placement and leg length with offset is what surgeons are most excited about. This technology can result in benefits to surgeons and patients.”

Surgeons are provided with a pre-operative 3-D reconstruction of the patient’s hip which is used to develop the patient-specific surgical plan. The robotic-arm then assists the surgeon during the procedure to accurately prepare the joint and optimally place the hip implants.

—*WE* (September 26, 2011)

extremities

Insurance Giants Cover Ankle Implant

Small Bone Innovations, Inc. founded in 2004 by Viscogliosi Brothers, LLC, the New York-based merchant banking firm that specializes in the musculoskeletal/orthopedics sector, announced on September 27, 2011 that the health plans Humana, Inc. and UPMC Health will each cover SBI’s Star total ankle replacement system.

The STAR ankle is the only total ankle replacement system to be cleared through the FDA’s Premarket Approval (PMA) process. In the PMA process, the STAR ankle’s safety and effectiveness was compared with ankle fusion in a multi-year, multi-center, concurrently controlled, Investigational Device



STAR total ankle replacement system/SBi, Inc.

Exemption (IDE) study. The IDE study results, published in 2009, demonstrated STAR to be superior in efficacy and comparable in safety to fusion. The IDE and other study results also showed that the STAR ankle had better pain relief, greater clinical success, less blood loss and a shorter operating time than fusion.

The decisions by Humana and UPMC Health mean that STAR is available to approximately 175 million of all pri-

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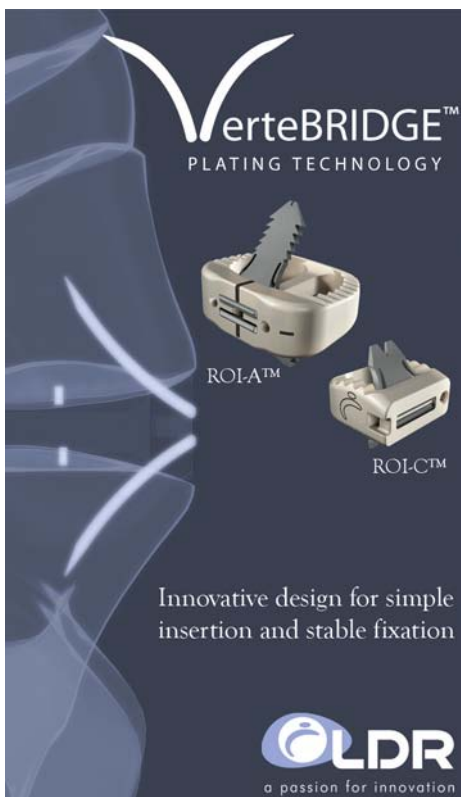
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vately insured health plan members in the U.S. In addition, almost all of the 100 million eligible individuals covered by governmental insurance programs, such as Medicare, Medicaid and TRICARE, also have access to the STAR ankle, as do nearly all individuals covered by state workers' compensation programs.

Roger A. Mann, M.D., co-lead investigator in the IDE study and co-author of a recent long-term study on STAR, said: "My studies of U.S. patients have demonstrated that the STAR implant is stable and functions for a long time—91% survival after 9.1 years. The STAR can also be utilized in ankles with a high degree of deformity and is the only total ankle joint replacement with a mobile bearing that has FDA PMA approval for implantation 'on-label' without the use of bone cement."

—BY (October 3, 2011)



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trauma

Osteoporosis: New Gene Identified

Making progress in understanding 'blast versus 'clast... Researchers at the Institut de recherches cliniques de Montréal (IRCM), directed by Dr. Jean Vacher, identified a new gene that modulates bone mass and that could become a risk factor for developing osteoporosis. Their work will be published October 5, 2011 in the scientific journal *Cell Metabolism*.

"The overall objective of our research is to understand the molecular and cellular mechanisms that determine the balance between bone formation and resorption (breakdown)," explained Dr. Vacher, Director of the Cellular Interactions and Development research unit at the IRCM, in the October 4, 2011. "Osteoblasts are responsible for making bones and work in synergy with osteoclasts, which reshape the bone. To gain insight into these complex mechanisms, we are studying the role of new genes that influence osteoclasts and osteoblasts."

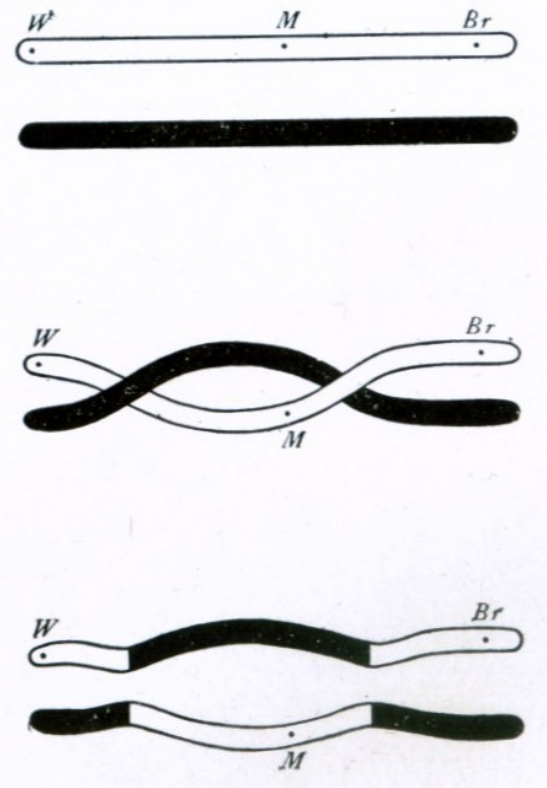
The team of researchers recently isolated a gene that modulates osteoclasts. They found, in mice, that a loss of this gene's function leads to a significant increase in the number of osteoclasts, thereby generating an even higher level of bone resorption.

"We identified this gene as a novel modulator of bone mineral density in mice and humans," added Dr. Vacher.

"More importantly, we showed that the human gene could represent a new susceptibility factor for osteoporosis. Hence, this discovery will help identify individuals with a greater predisposition to the disease who could benefit from preventive measures."

Mathieu Ferron, a graduate student from Dr. Vacher's laboratory, is the article's first author. This research project was conducted in collaboration with scientists at Université Laval in Québec and Washington University School of Medicine in St. Louis. Research carried out at the IRCM was funded by the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council of Canada (NSERC).

—EH (October 4, 2011)



Wikimedia Commons and Madeleine Price Ball

spine

Integra Launches Two New Products

Integra LifeSciences has introduced into the global market two new spinal implant products—the NewPort Minimally Invasive Spinal System (MIS) and the Steerable Intervertebral Body Fusion Device (IBD). Both systems expand Integra’s ability to offer surgeons user-friendly and intuitive minimally invasive systems for thoracolumbar spinal fixation procedures.

The company is featuring both systems at the Congress of Neurological Surgeons in Washington, D.C. and the Society of Minimally Invasive Spine Surgery in Las Vegas, Nevada.

Integra spokesmen report that the NewPort MIS System combines the Malibu System’s implant innovations with new instrumentation. The NewPort MIS System’s extended tab screws serve as built-in towers, which eliminate the additional profile and steps associated with placing a tower on the screw head.

They say that this addition provides not only a streamlined technique, but a secure screw-

tower connection that may limit the surgeon’s uncertainty of tower placement. Featuring two percutaneous rod deployment options, the NewPort MIS system provides surgeons flexibility in selecting the method that best suits their technique.

The Integra Steerable IBD is named for the user’s ability to “steer” the device into the proper anatomical position. The instruments, united with a broad selection of curved implants, deliver intraoperative versatility with a high level of control and precision for a minimally invasive transforaminal delivery. This could be critical, says the representative, when a surgeon is working in the smaller operative field required for minimally invasive procedures.

The combination of the NewPort System and the Integra Steerable IBD provide surgeons with a complete minimally invasive solution that simplifies the procedure.

In a testimonial for Integra’s new products, Dr. Chris Taleghani of Cumberland Brain and Spine in Hermitage, Tennessee, said, “Although the additional instrumentation required for minimally invasive surgeries adds a level of complexity to the procedure, the benefit to the patient is well worth the extra effort. The Newport system provides a user-friendly percutaneous approach and addresses a large portion of my needs for minimally invasive surgery.”

—BY (October 6, 2011)



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Acid-Etched Spine Device Cleared

Titan Spine, LLC, of Mequon, Wisconsin, has received FDA clearance to promote its Endoskeleton TAS system. The system consists of an ALIF device with integrated fixation screws and is the fifth regulatory clearance Titan Spine has received for its line of interbody implants.

Steve Cichy, vice-president for sales, explains that the acid etching on the device allows for greater surface to bone contact which promotes rapid mechanical fixation without risk of damage to the outer edge of the vertebral body. He says that the roughened surface provides up to 400% more contact than does a

smooth surface. The TAS also features three integrated grit-blasted screws that allow up to ten degrees of medial/lateral or anterior/posterior angulation.

Among the first surgeons to implant the device were Dr. Robert Henderson, an orthopedist with Dallas Spine Care, Dallas, Texas, and Dr. Fred Geisler, a neurosurgeon with the Chicago Back Institute, Chicago, Illinois.

Henderson commented, “The surgical technique was simple and straightforward. I am pleased Titan has added the supplemental fixation feature to its ALIF device that I have been using with great success to date. It is a nice option to have for specific spinal pathologies where supplemental posterior stabilization can be avoided.”

“I was particularly impressed with the purchase of the screws and how the roughened surface of the implant prevented the device from moving during screw insertion,” said Geisler. “The combination of immediate stabilization and the osteoinductive properties of the implant’s micro and nano textures represent a significant advance in spine surgery.”

Titan Spine, founded in 2006, is a privately-owned medical implant surface technology company that designs and manufactures interbody fusion devices for spine surgery.

—BY (October 4, 2011)



Titan Spine

THE PICTURE OF SUCCESS

Gunnar Andersson, M.D.

By Elizabeth Hofheinz, M.P.H., M.Ed.

Once upon a time those suffering from back pain had to choose from an array of elixirs and potions. And, while things progressed over time, when a certain curious Swede made his first strides into orthopedic medicine years ago, he wondered, “Where is the science?” Dr. Gunnar Andersson, Professor and Chair in Spinal Deformities at Rush University Medical Center, has created much of the science of back care.

Dr. Andersson, who is credited with designing the seat in Volvo automobiles, first came to the U.S. on a research fellowship in 1976. “I was an assistant professor at Gothenburg University and my chair presented me with the opportunity to work at Rush for a year. The chair, Dr. Jorge Galante, had spent three years in Sweden, and I had had the privilege of working with him there.”

A former president of the Orthopaedic Research Society, Dr. Andersson hails from a little town in Sweden...a town so small that he was the only child born the year he entered the world. “I was the first in my family to attend high school, but because there were no secondary schools available in the area, I had to go to boarding school at the age of nine. It was my godfather, a general practitioner, who influenced me as far as a

career in medicine. I was impressed by his ability to serve the local population and still maintain great sense of humor and a good quality of life.”

Dr. Andersson would go on to all that and more...he would find out what *lays behind* patients’ pain. When asked about the research he is most proud of, Dr. Andersson cites the work that won the Rush Spine Research Group this year’s Kappa Delta Award. “One of my NIH [National Institutes of Health] grants was to study lifting, twisting and other activities at work. From that I began working on disc degeneration and then more recently I have worked with others to use growth factors, cell therapy, and gene therapy to reverse degeneration...that is what led to the The Kappa Delta Award.”

“I continue to work on disc degeneration and am looking at how to tie degenerative changes occurring in the discs and elsewhere to the development of pain—and how to stop or reverse the progression of pain. The problem now is that while we know we can influence the process of disc degeneration in animals if we do it at the early stages of degeneration, once you get beyond a certain stage then the process doesn’t seem reversible. It will be a substantial challenge to move from animal work to



Gunnar Andersson, M.D.

humans; as of yet we have no approved clinical applications, nor FDA approval. This will happen in the next decade.”

Not forgetting where he came from, Dr. Andersson also looks back to his early years in Sweden for some of his most interesting work. “One of my first manuscripts involved studying people with hip replacements using different clinical methods of evaluating patients. In the process we found that my material was either the best or the worst ever published depending on the method used; I was pleased to be able to derive one appropriate outcome measure that was well received. I wanted the medical community to understand that published results depend on which outcome they used, i.e., you cannot compare one study to the next unless they use the same measures. In spine we have generally come to agreements about which methods to use.”

Dr. Andersson, who credits his “stubbornness” for much of his success, says,

“I am proud of my initial work on measuring the loads on spine using disc pressure measurements and EMGs on back muscles. This work resulted in the development of several biomechanical models of the spine; in particular, the model that Al Schwartz and I developed which was the first biomechanical spine model with some degree of sophistication. We were able to validate our model using invasive methods such as disc pressure measurements.”

So how did orthopedics get lucky enough to attract the likes of Dr. Andersson? Pure chance, says he. “I was looking for a summer job during medical school and I ‘landed’ in the orthopedics department. In general surgery I had just been cutting and suturing, but in orthopedics I got to expand on that by using nails, screws, rods, etc. However, I rapidly learned that the science wasn’t there. Many things we were doing were not well documented. I said, ‘Here is an area of tremendous opportunity.’”

After the research fellowship at Rush, Dr. Andersson returned to Sweden, where he had already completed a Ph.D. program. This, says the good doctor, was life altering. “It was at the outset of my doctoral studies that I made a deep commitment to being a clinician-scientist. I enjoyed my Ph.D. program so much that I could hardly wait to get to work. I was studying how sitting affects the spine; I measured the mechanical effect of sitting using electrical activity of the muscles and the pressure inside the vertebral disc. I used a mathematical model to calculate loads that the spine was subjected to when sitting in different chairs.”

A practical, top drawer car manufacturer would only want a practical, top drawer researcher to further its attempts to make a better vehicle. Dr. Andersson:

“This research, sponsored by Volvo, was the beginning of a long-term relationship I had with the company. I worked closely with the car designers, and I was very impressed that they wanted to cre-

ate good seats; they didn’t limit me or our team in any way in terms of what we wanted to explore. They wanted to approach the issue of comfort with this question in mind, ‘Is there a physiologic

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basis for the features we are thinking of introducing?' At that time few car seats had lumbar supports, so they were way ahead of the game. One of our primary findings was that lumbar support was really important to unload the spine when you sit. It is a combination of features in the seat that impact the spine loads; particularly important was the inclination of the backrest, the position and size of the lumbar support, and the inclination of the seat pan." (Dr. Andersson thinks of these things even years later as he drives his Volvo around Chicago.)

Moving to the U.S. permanently in 1985, Dr. Andersson joined Rush and got to work deciphering his new environment. "When I moved to the U.S. it was quite a change to go from a socialized medical environment to one where there is a business and legal aspect to most of your decisions. I prefer this, however, because I think the U.S. medical environment stimulates people to work harder and better."

As a leader, Dr. Andersson is not afraid to share the spotlight. Indeed, says he, that is what good leaders do. "I have never been interested in micromanaging, but instead I prefer to visualize the future and chart its direction. I like to allow others to develop and expand—and as a consequence everything gets better. Early on I learned that one of the keys to success is surrounding yourself with people who are more talented than you because they make you look better."

Describing a "career highlight," Dr. Andersson reflects on his time as president of the Orthopaedic Research Society (ORS). "I had always loved the mission of the ORS, namely, to promote basic science, so I was incredibly honored to be named president in 2000. While we are on the verge of new era



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characterized by an increasing emphasis on biologic solutions to musculoskeletal problems, it is hard to know how long it will take. Ten years ago I thought we would be further along than we are today. One problem with biologics is that it has been difficult to find a way of providing the appropriate amount of growth factor to stimulate bone healing at the right time in the process and at the right dose. Side effects are always a concern; also, if the dose is not high enough then it will not have an effect. Ultimately, this work is an issue of resources...when the funding community sees the laborious regulatory pathway people step back and say, "Why should we take a risk in this area when there are other areas where the risk is smaller?"

When asked what words of wisdom he would offer to future generations of orthopedic surgeons, Dr. Andersson states, "If I were young today I would go into spine. It is simply fascinating, with a substantial amount of interest-

ing technology, and a lot of room for growth. It is still an area where a young surgeon can contribute scientifically. At the same time it is an area where fewer people get completely well than in many other areas of orthopedics. If you're looking for 100% in outcomes... avoid spine."

An active athlete, Dr. Andersson says that in his youth he actually skied to school for three months a year. "I still enjoy skiing and running, and sometimes do these activities with my wife and two children. My wife? Well, she makes me look good. And our children—a son who is in banking and a daughter who works for a non profit—are just a delight. We all enjoy good food and wines, and I enjoy rummaging through my wine cellar, rotating bottles and taking note of what I should drink in the next several months and what can keep longer."

Dr. Gunnar Andersson...better with time. ♦



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